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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/787,415	02/27/2004	Toru Yano	Q80109	4540
65565 7590 06/14/2007 SUGHRUE-265550 2100 PENNSYLVANIA AVE. NW WASHINGTON, DC 20037-3213			EXAMINER TOSCANO, ALICIA	
			ART UNIT 1712	PAPER NUMBER
			MAIL DATE 06/14/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/787,415	<b>Applicant(s)</b> YANO ET AL.	
	<b>Examiner</b> Alicia M. Toscano	<b>Art Unit</b> 1712	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 May 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,7,9 and 14-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,7,9 and 14-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

1. Previous 112 rejection has been overcome by amendment.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1, 7 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kumazawa (JP 2003-096285) in view of Kuroki (WO 03/006550, US 6984443 is used as an Equivalent English Translation of the WO document).

Kamazawa includes elements of the invention as discussed in the action dated 3/9/06. Kamazawa discloses mixing D-lactic acid resins with L-lactic acid resins [0012]. This blend forms a polylactic acid stereo complex that has a high melting point, leading to a resin that has superior moldability. The blending ratio of D and L lactic acid is 90:10 to 10:90, meeting the range requirements of newly amended Claim 1.

Kumazawa does not include the use of a poly(D-lactic acid-co-saccharide). Kuroki includes elements of the invention as disclosed in the action dated 6/27/06. In addition, Kuroki discloses poly(L-lactic) and poly(D-lactic) acid homopolymers to be functional equivalents to poly(L-lactic) or poly(D-lactic-co-saccharide) copolymers (Column 4 Lines 18-61).

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It would have been obvious to one of ordinary skill in the art at the time of the invention to include in Kamazawa the use of poly(D-lactic acid-co-saccharide), as taught by Kuroki, as it is recognized by the art as a functional equivalent of poly(D-lactic acid).

The copolymer comprises at least 60 mol% lactic acid units (Column 4 Line 5), thereby encompassing a sacharride range of 0-40 mol%, as required by Claims 14-16.

Remarks:

Applicant argues that though the range of 90:10 to 10:90 is disclosed by JP '285, the combination of JP '285 and Kuroki does not teach or suggest the criticality of the claimed ratio. Applicant further argues that there is nothing cited in the prior art which suggests that an enhanced crystallization rate is obtained.

Examiner disagrees. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation see *In re Aller*, 105 USPQ 233, 235 (CCPA 1955) and *In re Hoeschele*, 160 USPQ 809 (CCPA 1969). Further, that the prior art does not recognize an enhanced crystallization rate is moot since said property is not claimed. Even if it were claimed, it must be inherent in the composition since the compositional requirements are met.

2. Claims 1, 7 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kumazawa in view of Shinoda (US 5247013).

Kamazawa includes elements of the invention as discussed in the action dated 3/9/06. Kamazawa discloses mixing D-lactic acid resins with L-lactic acid resins [0012]. This blend forms a polylactic acid stereo complex that has a high melting point, leading to a resin that has superior moldability. The blending ratio of D and L lactic acid is 90:10 to 10:90, meeting the range requirements of newly amended Claim 1.

Shinoda discloses biocompatible polyester resins. Said resins are L- or D-lactic acid-co-saccharide (Column 4 Lines 30-42). The use of the saccharide in the copolymers results in improved hydrolyzability (abstract). The saccharide may be a starch (Column 5 Line 31).

It would have been obvious to one of ordinary skill in the art at the time of the invention to include in Kumazawa the use of poly(d-lactic acid)-co-saccharide, as taught by Shinoda, in order to increase the hydrolyzability of the resin.

The saccharide is added in an amount from 0.001-1% by mole. Table 1 discloses the wt% of various saccharides to range from 0.02-20 wt%. This range meets the requirements of Applicants Claims 14-16.

3. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kumazawa and Kuroki or Kumazawa and Shinoda in further view of Oya (JP 08073628 A).

Kumazawa and Kuroki or Kumazawa and Shinoda include elements as set forth above. Kumazawa and Kuroki or Kumazawa and Shinoda do not include the use of a heated mold when molding an article from the polylactic composition.

Oya discloses a method for producing a polylactic acid resin with high heat resistance. Oya discloses that though polylactic acid polymers have excellent biodegradability said polymers have insufficient heat resistance. Said heat resistance is improved by crystallization via annealing of the lactic acid polymer. Said crystallization is produced by molding the polymer in a heated mold set at a temperature at least 20 degrees lower than  $T_c$ . It is the Examiners position that a molding temperature of 20 degrees lower than  $T_c$  encompasses the Applicants claimed range since the compositional requirements are met by Kumazawa, Kuroki and Shinoda and since both Applicants and Oya are disclosing the use of a heated mold in order to improve the heat resistance (See Applicants Specification pg 14).

It would have been obvious to one of ordinary skill in the art at the time of the invention to include in Kumazawa and Kuroki or Kumazawa and Shinoda the use of a heated mold, as taught by Oya, in order to improve the heat resistance of the resin.

### ***Conclusion***

### ***Response to Arguments***

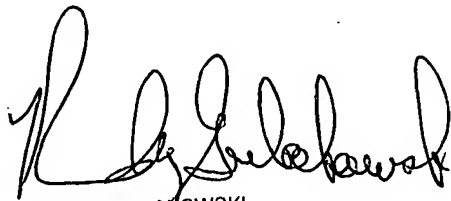
4. Applicant's arguments with respect to claims 1, 7-9 and 11-13 have been considered but are moot in view of the new ground(s) of rejection. Applicant argues the amended Claims is not longer met by the teachings of Kuroki and Kumazawa. Examiner agrees, and makes new grounds of rejection above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia M. Toscano whose telephone number is 571-272-2451. The examiner can normally be reached on Monday to Friday 8:30 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on 571-272-1302. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMT



RANDY GULAKOWSKI  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1700